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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MCINTOSH III, TRAVISS C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,111	SAS ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

It is noted that the preliminary amendment filed on 4/20/2005 has been considered and entered. The specification has been amended to include the priority data as requested.

Information Disclosure Statement

The Information disclosure statement filed on July 2, 2004 has been considered and a signed and initialed copy is attached.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-8 of copending Application No. 10/690,914. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating viral infections using

bicyclic carbohydrate compounds. It is noted that the instant application is drawn to methods of treating infections caused by *Flaviviridae* sp. and the '914 application is drawn to treating pathogenic viral infections, however, it is noted that infections caused by *Flaviviridae* are seen to be encompassed by the group of pathogenic viral infections. Moreover, it is noted that *Flaviviridae* are envelope viruses, and dependent claims of the '914 application limit the virus to herpesviridae or cytomegalovirus, which are also both known in the art to be envelope viruses. As such, it would be obvious to treat various envelope viruses with the same therapy, as seen by Wright, for example (US 6,034,073). One of ordinary skill in the art would understand that these applications are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-8 of copending Application No. 10/752,792 in view of Sas et al., 2003/0158243. Although the conflicting claims are not identical, they are not patentably distinct from each other. It is noted that the instant application is drawn to methods of treating viral infections and the '792 application is drawn to treating protozoal infections, however, Sas et al. bridges the nexus wherein Sas et al. teaches that this class of compounds (bicyclic carbohydrate derivatives) is effective in treating bacterial, viral, fungal, or protozoal infections. As such, the instant application is seen to be obvious in view of the '792 application and the teachings of Sas et al.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/663,962. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant application is drawn to methods of treating viral infections using the compounds of claim 1, which do not have halogen moieties in the R_4 aryl group. The '962 application is drawn to treating overlapping viral infections with compounds having the same core structure, but with halogen moieties on the R_4 aryl group. Halogen moieties are known in the art to be common leaving groups, as such, the examiner believes it would be obvious to one of ordinary skill in the art that the methods of the instant application and the methods of the '962 application are obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that claims 1-7 may also be rejected as being obvious variants of the methods of application 09/977,478. The method claims in the '478 application currently stand as being withdrawn, however, if they were rejoined, and depending on the scope of the product being administered, the instant claims may also be rejected as being obvious over the method claims of the '478 application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using compounds having O as the X moiety, does not reasonably provide enablement for using compounds having N or S as the X moiety. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

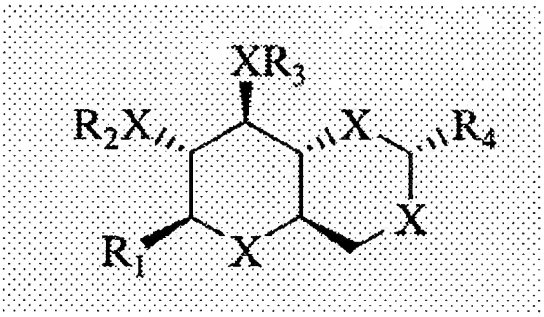
Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in ***In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)***. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims - The nature of the invention

Claim 1 is drawn to a method of treating *Flaviviridae* infection by administering a compound having the following formula:



wherein the X groups are O, N, or S. Claims 3-7 limit the various viruses to be treated.

The state of the prior art

Chemical compounds are know to be diverse in structure and function. Chemistry is not an exact science and is highly unpredictable. Antiviral agents are known to vary in their mode of action, and their effectiveness.

The level of predictability in the art

The examiner acknowledges the probability and predictability that the active agent has efficacy as claimed wherein X is O. However, one of ordinary skill in the art would not believe that the compounds wherein X is S or N would have efficacy as asserted. It is noted that the compound would have multiple charged ions when X is N, as there would only be 2 bonds attached to N. One of skill in the art would expect compounds having different chemical cores to have different activities.

The amount of direction provided by the inventor

The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to use the claimed method commensurate in the scope with the instant claims. There is a lack of data and examples which adequately represent the scope of claim as written. The examiner notes, there has not been provided sufficient instruction or sufficient methodological procedures to support the alleged efficacy instantly asserted using a compound from the broad group of claim 1. The compounds produced by the instant application are taught to be made from sugar molecules, and one of ordinary skill in the art would not be able to extrapolate from the methods of making as set forth in the instant application methods of making non-sugar compounds, i.e., S and N containing compounds.

The existence of working examples

The working examples set forth in the instant specification are directed to the use of only compounds having O in the X position. There has not been provided sufficient evidence which would warrant the skilled artisan to accept the data and information provided in the working examples as correlative proof that any compound of claim 1 would indeed provide antioxidant activity.

The quantity of experimentation needed to make and use the invention based on the content of the disclosure

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable the use of any compound of claim 1 as an antiviral agent without undue experimentation. One skilled in the art could not use the entire scope of the claimed invention without undue experimentation. One skilled in the art would be confronted with an undue burden

of experimentation to prepare, characterize, and test the various compounds of claim 1 to determine if indeed they have efficacy as antiviral agents. As set forth supra, applicants have successfully shown methods of treating the claimed viral diseases using compounds having O in the X position.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 provides that the method can be practiced with the compound as claimed, or a pharmaceutically active derivative thereof. It is unclear as to what exactly is encompassed by a "derivative". In the absence of the identity of moieties intended to modify an art recognized chemical core, described structurally or by chemical name, the identity of a derivative would be difficult to ascertain. In the absence of said moieties, the claims containing the term "derivative" are not described particularly sufficiently to distinctly point out that which applicant intends as the invention. It is noted that the examiner is interpreting this phrase to include any compound which is pharmaceutically active in treating the viruses claimed, which must be a derivative of the claimed compound. Since there is no definition for derivative, any compound could technically be a derivative with enough chemical derivatizations.

Claim 1 is also indefinite wherein the structural formula set forth in the claim has dangling valences when X is N, which leaves uncertainty as to exactly what is to be encompassed by the instant claims.

Claim 6 is indefinite wherein the claim is drawn to a method as defined in claim 4, wherein the virus is hepatitis C. However, claim 4 provides the virus is BVDV. It is unclear how BVDV can be further limited to HCV. Moreover, claim 3 already limits the method of claim 1 to treating HCV.

Claim 7 is indefinite wherein the claim is drawn to a method as defined in claim 3, wherein the virus is BVDV. However, claim 3 provides the virus is HCV. It is unclear how HCV can be further limited to BVDV. Moreover, claim 4 already limits the method of claim 1 to treating BVDV.

All claims which depend from an indefinite claim are also indefinite. ***Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).***

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Tam (US 6,518,253).

The claims of the instant application are drawn to methods of treating HCV by administering the compound of claim 1 or a "pharmaceutically active derivative thereof". It is noted that the specification is not seen to provide guidance to define that which applicant intends by the phrase "or a pharmaceutically active derivative thereof". As such, the examiner has given this the broadest reasonable interpretation in light of the specification, which would read on any compound which is pharmaceutically active, and also a derivative. Because compounds can be made from one another, and there is no limitation on the number of derivations which can be performed on the compound, theoretically, any compound which is pharmaceutically active is also seen to be a derivative. Moreover, because claim 2 limits the compound of claim 1, it does not require the compound to be administered, a pharmaceutically active derivative may still be administered.

Tam teaches of methods of treating HCV using the L-isomer of ribavirin (see abstract). Ribavirin is seen to be pharmaceutically active, and is also seen to be a derivative of the compound of claim 1, as ribavirin is known to be a sugar based compound.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Dykstra et al. (US 2003/0199521).

The claims of the instant application are drawn to methods of treating HCV or bovine viral diarrhea (BVDV) by administering the compound of claim 1 or a "pharmaceutically active derivative thereof". It is noted that the specification is not seen to provide guidance to define that

which applicant intends by the phrase "or a pharmaceutically active derivative thereof". As such, the examiner has given this the broadest reasonable interpretation in light of the specification, which would read on any compound which is pharmaceutically active, and also a derivative. Because compounds can be made from one another, and there is no limitation on the number of derivations which can be performed on the compound, theoretically, any compound which is pharmaceutically active is also seen to be a derivative. Moreover, because claim 2 limits the compound of claim 1, it does not require the compound to be administered, a pharmaceutically active derivative may still be administered.

Dykstra et al. disclose methods of treating HCV or BVDV using various compounds (see [0012]). The compounds as set forth in Dykstra are seen to be pharmaceutically active, and are also seen to be a derivative of the compound of claim 1.

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Sas et al. (US 2003/0158243).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims of the instant application are as set forth supra.

Sas et al. disclose that their compounds have efficacy as antiviral agents (see table 2 on page 10, and [0073]-[0076]). As such, claims 1 and 2 are seen to be anticipated by Sas et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2/2/06

Shaojia A. Jiang
Supervisory Patent Examiner
Art Unit 1623

Traviss C. McIntosh
February 2, 2006